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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/651,651

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Michael Lassner

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1981

7590

06/14/2006

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EXAMINER

KALLIS, RUSSELL

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/651,651

Applicant(s)

LASSNER ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,22,28,34,36,38,40-43,45-50,107,111,115,117 and 123-125 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10,22,28,34,36,38,40-43,45-50,107,111,115,117 and 123-125 is/are rejected.
- 7) ☒ Claim(s) 113 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Rejection of Claims 10, 22, 28, 32, 34, 36, 38, 40 and 121-125 under 35 U.S.C. 102(a) is withdrawn in view of Applicant's amendments.

Rejection of Claims 43, 46-47 and 49-50 under 35 U.S.C. 112, second paragraph is withdrawn in view of Applicant's amendments.

Claims are 10, 22, 28, 32, 34, 36, 38, 40-43, 45-50, 107, 111, 113, 115, 117 and 121-125 are pending and examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 10, 22, 28, 34, 36, 38, 40-43, 45-50, 107, 111, 115, 117 and 123-125 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/16/2004, 6/16/2005 and 12/19/2005. Applicant's arguments filed 3/21/2005, 9/19/2005 and 3/20/2006 have been considered but are not deemed persuasive.

Applicant asserts that the written description requirement does not require an exact description of the claimed subject matter but rather the invention must clearly allow one of ordinary skill in the art to recognize the invention, and that it must be viewed from the perspective of one of skill in the art at the time of filing (response page 7). Applicant has claimed

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a genus of isolated polynucleotides yet has not defined that genus with respect to any specific structural features common to that genus wherein those common features are correlated with a common function, and thus the written description fails to recite any specific function or activity associated with the claimed genus, and hence has not provided an adequate written description of the invention as broadly claimed.

Applicant asserts by further elaborating that techniques for amino acid substitution and the analysis thereof are well known in the art and discusses hydrophobicity and hydropathy analysis with respect to protein modification (response pages 7 and 8). Applicant has not presented any coding sequences that have been modified or analyzed with respect to their hydrophobicity and hydropathy as discussed. Although it may be a common practice to make changes Applicant has not described which changes one would make to the claimed invention to retain the inherent properties of the isolated sequence.

Applicants remarks directed to the Noiriell reference (Noiriell A. *et al.* European Journal of Biochemistry, 2004; Vol. 271, pages 3752-3764) on pages 8 and 9 of the response clearly show that Applicant was not in clear possession of the invention as broadly claimed at the time of filing. Using Applicant's arguments above that one must view the invention from the perspective of one of skill in the art at the time of filing, the finding of the Noiriell paper shows clearly that the perspective of one of skill in that art had not yet resolved a common specific activity for the LCAT-like sequence disclosed in the reference. Further, with respect to Applicant's assertions that the reference teaches that the LCAT2 polynucleotide sequence encodes a sterol acyltransferase it would be remiss on the Examiner's part not to point out that

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the claims are drawn to lecithin: cholesterol acyltransferase-like activity not phospholipase-A sterol acyltransferase activity as taught by Noriel *et al.*

Applicant asserts that there is no basis in law to limit Applicants to any less than what is being claimed (response page 8). See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). “A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.”

Applicants fail to describe a representative number of isolated polynucleotides having at least 80% sequence identity to SEQ ID NO: 4; and isolated polynucleotides that hybridize to SEQ ID NO: 4. Further, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Moreover, Applicant has not described the specific activity or function of the claimed genus of polynucleotides, and thus has not described the genus as broadly claimed.

Claims 10, 22, 28, 34, 36, 38, 40-43, 45-50, 107, 111, 115, 117 and 123-125 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a recombinant vector comprising an isolated polynucleotide of SEQ ID NO: 4 or an isolated polynucleotide encoding a polypeptide of SEQ ID NO: 5, and plants transformed therewith having increased total oil content in transformed seeds, does not reasonably provide enablement for any non-exemplified polynucleotides which are at least 80% complementary to SEQ ID NO: 4; or for non-exemplified polynucleotides that hybridize to SEQ ID NO: 4 under low stringency conditions; or plants transformed therewith in sense or antisense orientation that produce

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transformed seeds having an increase in sterol-esters, oil content or sterol content; or for plants transformed with LCAT2; i.e. SEQ ID NO: 4 producing transformed seeds having increased sterol-ester or increased phytosterol content or any non-specified alteration in oil production. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/16/2004, 6/16/2005 and 12/19/2005. Applicant's arguments filed 3/21/2005, 9/19/2005 and 3/20/2006 have been considered but are not deemed persuasive.

Applicant asserts that it is routine in the art to make changes to coding sequences and then assay for activity and states that The Detailed Description of the Invention describes those techniques that will retain or improve enzymatic activity (response page 10-12). Applicant has not set forth an enzymatic activity for LCAT 2; SEQ ID NO: 4 encoding SEQ ID NO: 5 or an assay that to distinguish it from what is known in the art. Further, Applicant has not provided working examples of enzymatic variants for any LCAT proteins taught in the specification.

Further, Applicant's response that no conclusions can be made with respect to the LCAT2-like sequence does not fully acknowledge that the enablement art teaches that a likely candidate for lecithin:cholesterol acyltransferase (LCAT2; i.e. SEQ ID NO: 4) unexpectedly showed phospholipase A1 activity when transformed into Arabidopsis resulting in the accumulation of triacylglycerol (TAG) and fatty acids (FA) but no increases in sterol-esters (SE) demonstrating not only that LCAT2 is not an lecithin:cholesterol acyltransferase but also teaching that making assumptions about LCAT2-like sequences is unpredictable. (Noiriel A. *et al.* European Journal of Biochemistry, 2004; Vol. 271, pages 3752-3764; see Abstract lines 1-7;

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cloning of LCAT-like cDNAs on page 3753 in column 2; page 3757 column 2 beginning with line 4; and the Discussion beginning on page 3761 to page 3762 column 1 line 4; and bibliography reference 48a on page 3763).

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified polynucleotide sequences encoding non-exemplified LCAT2-like polypeptides (i.e. polynucleotides , by producing expression vectors to transform plants therewith and test for product formation, in order to identify those polynucleotides that when over-expressed or expressed in antisense orientation would produce plants that yield an increased oil content or some non-specified altered oil content in transformed seeds.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled throughout the broad scope of the claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claim is allowed.

Claims 10, 22, 28, 34, 36, 38, 40-43, 45-50, 107, 111, 115, 117 and 123-125 are deemed free of the prior art given the failure of the prior art to teach or reasonably suggest plants or plant cells transformed with a recombinant construct comprising SEQ ID NO: 4 or host cells comprising SEQ ID NO: 4 that express SEQ ID NO: 5.

Claim 113 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the allowable limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Russell Kallis Ph.D.
June 9, 2006

RUSSELL P. KALLIS, PH.D.
PRIMARY EXAMINER

A handwritten signature in cursive script that reads "Russell Kallis".